DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

g14704

CERTIFIED MAIL
RETRUN RECEIPT REQUESTED

WARNING LETTER
2001-DT-23

June 26, 2001

Mr. Michael Blanchard
Facility Administrator
Community Hospital - South
1402 East County Line Road South
Indianapolis, IN 46227

Dear Mr. Blanchard:

We are writing you because on June 20, 2001, your facility was inspected by a representative of the State of Indiana acting in behalf of the Food & Drug Administration (FDA). The inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following Repeat Level 2 finding at your facility:

One (1) of six (6) random medical reports reviewed did not contain an acceptable assessment category for your facility, Community Hospital South.

The specific problem noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which your facility received at the close of the inspection. This problem is identified as a Repeat Level 2 because it identifies a failure by your facility to implement permanent correction of the same problem found during your previous inspection.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without

further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10, 000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- the specific steps you have taken to correct the Repeat Level 2 violation noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- sample records that demonstrate proper record keeping procedures. (Note: Patient names or identification should be deleted from any copies submitted.)

Please submit your response to: Mr. David M. Kaszubski
Director Compliance Branch
U. S. Food & Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207-3179

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter only pertains to findings of your inspection and does not necessarily address other obligations you have under law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have any questions regarding this letter or how to ensure that you are meeting MQSA standards, please call Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,

for David M. Kazubski
Raymond V. Mlecko
District Director
Detroit District

Enclosures: a/s